IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

TAMIA CLARK, the surviving minor child of Chandra Clark, by her next friend and legal guardian Linda Clark, Plaintiff, v. GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC CORPORATION and JOHN DOES I THRU X, Defendants.	CASE NO. 1:08-CV-2230-JOF

PLAINTIFF'S MEMORANDUM OF LAW IN RESPONSE TO DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT

COMES NOW TAMIA CLARK, the surviving minor child of Chandra Clark, by her next friend and legal guardian Linda Clark ("Plaintiff"), and files this, her Memorandum of Law in Response to Defendants' Motion to Dismiss

Plaintiff's Second Amended Complaint[1] and shows this Honorable Court the following:

INTRODUCTION AND FACTUAL BACKGROUND

Because the Defendants have filed a motion to dismiss, the controlling facts are the allegations of the Second Amended Complaint ("SAC") coupled with the allegations of the First Amended Master Complaint ("FAMC") which was filed in the Guidant Multi-District Litigation ("MDL") captioned *In re Guidant Defibrillators Product Liability Litigation*, Case No. 05-MD-1708 (D.Minn.). The Plaintiff attached and incorporated by reference the FAMC in the SAC.

As will be discussed further below, the SAC provides details specific to Plaintiff's case regarding the particular device implanted in Chandra Clark and the nature of Plaintiff's damages. The FAMC details the issues with Guidant defibrillators, violations of federal regulations and other details which support Plaintiff's claims.

In the very first paragraph of the SAC, Plaintiff makes clear that (1) Chandra Clark was implanted with one of Defendant's pacemakers, the Vitality 2 VR IS-

[1] Plaintiff filed her Amended Complaint in Gwinnett State Court, prior to removal, on June 13, 2008 to change a paragraph regarding the corporate status of Guidant. On July 15, 2008, Plaintiff filed her Second Amended Complaint in this Court to correct typographical errors in paragraphs one and two.

1/D Model T175, on May 26, 2005 (2) that the pacemaker was manufactured, sold and/or serviced by Defendants; and (3) Chandra Clark died on July 10, 2006 as a proximate result of a dangerous defect in the pacemaker. (SAC ¶ 1.)

On July 10, 2006, Chandra Clark underwent an outpatient laparoscopic surgery on her gall bladder at Atlanta Medical Center. (SAC ¶ 14.) While unconscious and under anesthesia, Chandra Clark began to experience bradycardia, which led to cardiac arrest and her death, because the pacemaker malfunctioned, failing to return her heart to its proper rhythm due to the defective condition of the pacemaker. (SAC ¶ 15.)

Approximately two weeks after Chandra Clark's death, Defendant Guidant issued a Class II recall of the model pacemaker that was implanted in Chandra Clark. (SAC ¶ 19.) The recall was based on two known failure modes: (1) premature battery depletion; and (2) defective low voltage capacitor. (*Id*.)

Plaintiff clearly alleges that prior to Chandra Clark's death, Guidant knew or should have known that this pacemaker was dangerously defective, that it posed a risk of death or serious injury to patients implanted with it and that those dangers warranted an immediate recall. (SAC ¶ 20).

Additionally, Plaintiff specifically alleged that her claims are not preempted by FDA pre-market approval to the extent that: (1) The Defendants

misrepresented the characteristics of the device; (2) The Defendants violated the UCC warranty of fitness; (3) The Defendants violated standards of general applicability which are not specific to the particular design of the subject device; (4) The Defendants did not have a valid Pre-Market Approval ("PMA") in effect at the time of the injury, or the PMA was void due to a material violation of its conditions; (5) The Defendants materially deviated from the functional requirements set forth in the application for the PMA or any supplemental PMA which were adopted by the FDA, and there is a causal nexus between the deviation and the injury; (6) The Defendants made changes in design, manufacturing process, labeling, instructions and warnings, or "any other attribute that would affect safety or effectiveness" of the product without FDA approval; or (7) The Defendants otherwise violated federal requirements. (SAC ¶ 70.)

Finally, the SAC sets forth Plaintiff's claims for Strict Liability for Design Defect (SAC ¶¶ 22-30), Strict Liability for Manufacturing Defect (SAC ¶¶ 31-41), Strict Liability for Failure to Warn (SAC ¶¶ 42-48), Breach of Express Warranty (SAC ¶¶ 49-54), Breach of Implied Warranty (SAC ¶¶ 55-59) and Negligence (SAC ¶¶ 60-63).

Turning to the FAMC, the 133 page pleading sets forth in detail how the Defendants' devices work and their specific components (FAMC ¶¶ 45-56) (the

defects of Defendants' devices). It also clearly alleges that Guidant failed to meet federal regulations applicable to medical devices which proximately caused them to be in violation of federal law and led to the injury and death of the plaintiffs and/or the plaintiffs' decedents. (FAMC ¶ 74.) Critically, the FAMC gives a history of the devices, Defendants' specific knowledge of defects in their devices, and that Defendants' failed and flawed disclosures failed to meet FDA regulations and violated conditions for the approval of the devices. (FAMC ¶¶ 75-83.). Defendants "concealed, omitted, and suppressed this material information, preventing Plaintiffs, the medical community, regulators and the public from making informed choices about the use of the Devices." (FAMC ¶ 83.)

The FAMC, which Plaintiff specifically attached and incorporated into the SAC, details Defendants failure to meet manufacturing and regulatory standards, listing fifteen observations of violations noted by the FDA during an inspection of Defendants' facilities. (FAMC ¶¶ 170-179.) Additionally, Defendants failed to obey FDA regulations and Conditions of Approval with respect to PMA and PMA supplements. (FAMC ¶ 176.) Defendants designed and/or manufactured the devices in a way that violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 *et seq*. (FAMC ¶ 280.)

Upon reading Plaintiff's SAC and the FAMC together, it becomes clear that Defendants manufactured, marketed and/or distributed devices, such as the one implanted in Chandra Clark, which were defective and that the device defects caused Chandra Clark's death. Further, Defendants violated numerous federal regulations which may serve as the basis for Plaintiff's state law claims.

PROCEDURAL BACKGROUND

This case was originally filed in the State Court of Gwinnett County, Georgia. Soon thereafter, Defendants removed this case to this Court. Defendants then filed a Motion to Stay All Proceedings and requested that this case be transferred to the previously aforementioned MDL litigation, *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, Case No. 05-MD-1708 (D. Minn.) This case was transferred to the MDL litigation on August 28, 2008. After a global settlement, of which Plaintiff opted-out, this case was remanded back to this Court on May 7, 2010. On June 30, 2011, the parties filed a Joint Motion to Lift Stay and Enter Proposed Responsive Pleading Schedule. This schedule called for Plaintiff to file her response to Defendants' Motion to Dismiss on August 19, 2011, and Plaintiff therefore, timely files this response pursuant to that deadline.

Notably, while this case was filed on June 4, 2008, it has been stayed for the majority of the last three years, Plaintiff has not been afforded the opportunity to proceed with discovery.

LEGAL STANDARD

Defendants move for the dismissal of Plaintiff's Second Amended Complaint on two grounds: (1) that federal law preempts all of Plaintiff's claims; and (2) that the complaint fails to plead sufficient facts to state a claim.

"There are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular." *Bausch v. Stryker Corp*., 630 F.3d. 546, 558 (7th Cir. 2010). In order to properly state a claim, a plaintiff need only "provide his/her opponent with 'fair notice of what [his] claim is and the grounds upon which it rests'" with "some brief factual description of the circumstances surrounding the acts or omissions upon which he bases his claim." *Atwater v. Nat'l Football League Players* Ass'n, CIVA 1:06-CV-1510-JEC, 2007 WL 1020848 (N.D. Ga. Mar. 29, 2007 (quoting *Parker v. Brush Wellman, Inc*., 377 F. Supp. 2d. 1290, 1294 (N.D. Ga. 2005) (Story, J.)). Further, in order to survive a motion to dismiss, courts do "not require heightened fact pleading of ***specifics***, but only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1960 (2007) (emphasis added).

When determining whether a motion to dismiss should be granted, "a court must construe the complaint in the light most favorable to the plaintiff and accept the plaintiff's allegations of material facts as true." *Eberhart v. Charter Communications, Inc.*, 518 F. Supp. 2d. 1374, 1376 (N.D. Ga. 2007) (Carnes, J.) (citing *Beck v. Deloitte & Touche*, 144 F.3d 732, 735 (11th Cir. 1998)). "A court may grant a motion to dismiss if it finds that the plaintiff cannot prove any set of facts consistent with the complaint which would entitle him or her to relief." *Eberhart v. Charter Communications, Inc.*, 518 F. Supp. 2d. 1374, 1376 (N.D. Ga. 2007) (Carnes, J.) (citing *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). Defendants bear "the 'very high burden' of showing that the plaintiff cannot conceivably prove any set of facts that would entitle him to relief." *Eberhart v. Charter Communications, Inc.*, 518 F. Supp. 2d. 1374, 1376 (N.D. Ga. 2007) (Carnes, J.) (citing *Beck* at 736).

As will be thoroughly demonstrated below, Defendants have failed to meet their burden as Plaintiff has adequately pled her case. As a result, Defendants' motion should be denied.

ARGUMENT

I. Plaintiff's Claims are Not Preempted

While Defendants are correct that 21 U.S.C. § 360(k) can preempt state law claims related to Class III devices which have received a PMA, such preemption does not sweep as broadly as Defendants suggest. *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008). Numerous post-*Riegel* courts have allowed plaintiffs to assert state law claims. [2]

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[2] *O'Shea v. Cordis Corp*., 2008 WL 3139428 (Fla. Cir. May 19, 2008) (parallel violation claims, including ones related to off-label promotions are not preempted, express warranty claims are not preempted); *Heisner v. Genzyme Corp*., 2008 WL 2940811 (N.D. Ill. July 25, 2008) (express warranty claims not preempted); *Purcel v. Advanced Bionics Corp*., 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008) (strict liability and implied warranty claims not preempted); *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. Oct. 20, 2008) (manufacturing defect claim not preempted); *Hofts v. Howmedica Osteonics Corp*., 597 F. Supp. 2d 830 (S.D. Ind. Jan. 12, 2009) (express and implied warranty and consumer fraud claims not preempted); *Horowitz v. Stryker Corp*., 613 F. Supp. 2d 271 (E.D.N.Y. Feb. 20, 2009) (manufacturing defect claim not preempted, express warranty claims escape preemption to extent not based on approved labeling); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243 (D.N.J. March 5, 2009) (express warranty claims are not preempted); *Mitaro v. Medtronic, Inc*., 23 Misc. 3d 1122(A), 886 N.Y.S. 2d 71, 2009 WL 1272398 (N.Y. Sup. April 9, 2009) (manufacturing defect claim could be parallel claim); *Williams v. Endologix, Inc*., slip op., 2009 WL 3554581 (Ky. Cir. Oct. 30, 2009) (claims based on FDCA violations not preempted); *Kallal v. Ciba Vision Corp*., 2010 WL 2330365 (N.D. Ill. June 9, 2010) (pleading based on violation of FDA standard was parallel claim); *Howard v. Sulzer Orthopedics, Inc*., 382 Fed. Appx. 436 (6th Cir. June 16, 2010)

Defendants' brief suggests that a miniscule window might exist for plaintiffs to bring state law claims, but that such a window is small because state law claims almost always impose additional requirements. *See Defs' Mem. In Supp.* pp.12-13. However, such is not the case. As one court has noted,

> The FDA regulatory system and a state tort system can and should work together. Each serve different, yet related, functions. A regulatory system ensures products on the market have a favorable risk-reward profile, and a tort system provides incentives to manufacturers to develop and maintain safe devices. In this way, private tort remedies strengthen federal standards.

In re Guidant Corp. Implantable Defibrillators Products Liab. Litig., MDL 05-1708DWF/AJB, 2007 WL 1725289 *11 (D. Minn. June 12, 2007).[3]

(unpublished) (allowing plaintiff to rely on FDA Good Manufacturing Practice regulations); *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 998 A. 2d. 543 (N.J. Super. A.D. July 23, 2010) (manufacturing defect claim based on FDA warning letter not preempted); *Warren v. Howmedica Osteonics Corp*., 2010 WL 5093097 (E.D. Mo. Dec. 8, 2010) (claims based solely on FDCA violations survive preemption); *Hughes v. Boston Scientific Corp*., 631 F. 3d 762 (5th Cir. Jan. 21, 2011), (violation claims which paralleled state warning and negligence per se claims not preempted); *Carrelo v. Advanced Neuromodulation Systems*, 2011 U.S. Dist. Lexis 40706 (D.P.R. March 8, 2011) (claims that plaintiff did not receive FDA approved warnings not preempted); *Gelber v. Stryker Corp*., 2011 WL 1483927 (S.D.N.Y. April 18, 2011) (manufacturing based claim, express warranty claims and implied warranty claims survive preemption).

[3] This opinion was rendered in the MDL case which this case was transferred to on August 28, 2008 and involves many of the claims and devices that were the subject of the FAMC.

Plaintiff will demonstrate below how she has alleged state law claims which are not subject to preemption.

a. Plaintiff has asserted parallel claims which survive preemption

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) and subsequent cases make clear that state law claims can be asserted when they are premised on a violation of FDA regulations. *Riegel* at 329. Both the SAC and FAMC allege parallel claims in that, pursuant to *Riegel*, they allege that specific federal regulations and/or requirements have been violated. (SAC ¶¶ 69-71) and (FAMC ¶¶ 74-83, 170-179). Therefore, contrary to Defendants' claim that Plaintiff is relying solely on the incantation of "magic words," (*See Defs' Mem. In Supp.* pp.16-17) Plaintiff has pointed to specific federal regulations violated.

In their brief, Defendants cite a two prong test that a plaintiff must meet to fit the "narrow exception" to preemption, that was developed by a California district court. See *Cohen v. Guidant Corp*., VCV-05-8070-R, 2011 WL 637472 (C.D. Cal. Feb. 15, 2011).[4] However, the United States Supreme Court in *Riegel* makes clear that the true test in determining whether state claims are preempted is an analysis which determines (1) whether there are federal requirements which

[4] It is worth noting that the plaintiff in the *Cohen* case was given the opportunity to file an amended complaint to address alleged deficiencies noted when the Court dismissed its First Amended Complaint. *Cohen* at 1.

apply to the device; and if so, (2) whether the claims are based on state law requirements with respect to the device that differ from or are in addition to the federal law requirements, and that relate to safety and effectiveness. *Riegel* at 321-322. A close reading of the SAC and FAMC demonstrates that Plaintiff's pleadings pass the *Riegel* test.

In attempting to persuade this Court to dismiss Plaintiff's SAC, Defendants rely heavily on *Wolicki-Gables v. Arrow Intern., Inc*., 634 F.3d 1296 (11th Cir. 2011) to argue that she has failed to state her parallel claims with sufficient specificity. However, there is one critical distinction between the present case and *Wolicki-Gables*. The district court, and ultimately the District Court of Appeals, were deciding *Wolicki-Gables* on a motion for summary judgment. As the district court noted, "…Rule 56(c) mandates the entry of summary judgment **after adequate time for discovery**…" *Wolicki-Gables v. Arrow Int'l, Inc*., 641 F. Supp. 2d 1270, 1277 (M.D. Fla. 2009) (emphasis added) quoting *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). The *Wolicki-Gables* courts were determining whether the plaintiffs had parallel claims after the benefit of discovery, including depositions. In the present case, Plaintiff has not taken any discovery which would provide the information to further detail her parallel claims. Unlike *Wolicki-Gables* where the court could consider deposition, documentary and other forms of

evidence to analyze whether the plaintiffs had parallel claims, here the court is limited to the pleadings to determine whether Plaintiff has **sufficiently pled** her parallel claims.

Even without the benefit of discovery, and without the benefit of the *Wolicki-Gables* decision which was decided almost three years after the SAC was filed, Plaintiff's allegations are sufficiently detailed. Indeed, the FAMC details FDA regulations violated (FAMC ¶¶ 75-83) and the findings of an FDA inspection of Defendants' facilities which listed some fifteen violations of federal regulations (FAMC ¶¶ 170-179), a specificity of allegations that did not seem to be present in the *Wolicki-Gables* case. Therefore, Plaintiff has indeed alleged violations of federal regulations. This meets the *Riegel* test, which was recognized by the *Wolicki-Gables* Court, and is sufficient to plead parallel claims.

b. The device at issue was recalled, which further supports Plaintiff's allegation that federal regulations were violated

Plaintiff alleged in her SAC that the specific pacemaker implanted in Chandra Clark was recalled approximately two weeks after her death due to two known failure modes: (1) premature battery depletion; and (2) defective low voltage capacitor. (SAC § 19). This recall related to the specific device at issue further supports Plaintiff's parallel claims. Product recalls have been considered in

cases where plaintiffs were found to have asserted parallel claims. In *Purcel v. Advanced Bionics Corp*., 3:07-CV-1777-M, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008) the court considered the fact that the device manufacturer issued a voluntary recall of the device. Notably, it also considered violations of federal requirements grounded in inspection reports documenting multiple violations of requirements, such as those listed in the FAMC. (FAMC ¶¶ 170-179).

In fact, one court took the use of recalls as a foundation for parallel claims one step further. In *Prudhel v. Endologix, Inc*., CIV S-09-0661LKK/KJM 2009 WL 2045559 (E.D. Cal. July 9, 2009), Plaintiff alleged that the device manufacturer had recalled batches of a type of stent, but they did not allege that the stent at issue in that case was subject to the recall. Regardless, the *Prudhel* court wrote, "Although plaintiffs do not specifically connect these recall allegations to any claim for relief, these allegations provide some indication of the type of defects alleged to exist." *Prudhel* at 2. The court ultimately held that the plaintiffs' strict liability manufacturing defect claim was a valid parallel claim, using as part of its reasoning that prior lots of the stent had been recalled.

Plaintiff's allegations are stronger than the plaintiff's in *Prudhel* because Plaintiff alleges that the specific device has been recalled. The recall of the specific device at issue in the present case and the inspections done at Defendants'

facility revealing violations, are allegations in Plaintiffs' SAC and FAMC that support her parallel claim.

c. A causal nexus exists between the parallel claims and Plaintiff's damages

As stated above, *Riegel* says nothing about the necessity of alleging a causal nexus between parallel claims and Plaintiff's damages. This is a requirement developed by the *Cohen* court. Even so, reading the SAC and the FAMC, the only reasonable conclusion that one can draw is that Plaintiff has sufficiently alleged that the Defendants have violated several federal regulations related to the device at issue that serve as the basis of Plaintiff's parallel claims and that those claims relate to Chandra Clark's death. "In ruling on a motion to dismiss, the court must accept the facts pleaded in the complaint as true and construe them in the light most favorable to the plaintiff." *Ciarlante v. Dollar Tree Stores, Inc*., 3:11-CV-9-TWT, 2011 WL 2135622 (N.D. Ga. May 31, 2011) citing to *Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., S.A.*, 711 F. 2d 989, 994-95 (11th Cir. 1983). As the court in *Sanjuan v. Am. Bd. of Psychiatry and Neurology, Inc.* wrote at the pleading stage, the plaintiff "receives the benefit of imagination." *Sanjuan* 40 F. 3d 247, 251 (7th Cir. 1994). Plaintiff's SAC

combined with the FAMC far surpasses the *Sanjuan* standard as her allegations provide sufficient details and leave little to the imagination.

The FAMC goes into detail regarding the FDA's findings of federal regulation violations at Defendants' facilities. Those violations went to the heart of the processes in place at the facilities where devices such as the one implanted in Chandra Clark were being manufactured. As Plaintiff specifically alleges in her SAC, Chandra Clark's device was defective and that defect led to her device not returning her heart to its proper rhythm once Chandra Clark suffered bradycardia. Such pleading is sufficient to put Defendants on notice of Plaintiff's claim and the causal nexus between the parallel claims and the injuries alleged.

II. Plaintiff's Second Amended Complaint is Sufficiently Pled

As the Supreme Court has written, the "Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the…claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007), quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957). For the purposes of a motion to dismiss a court must take all of the factual allegations in the Complaint as true.

In order to defeat a motion to dismiss, a plaintiff's Complaint must possess sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id*. at 556. The plausibility standard is not the same as a '"probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 1940-1941. However, "a well-pleaded Complaint may proceed even if it strikes a savvy judge that actual poof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" *Bell At. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (internal quotation marks omitted); *see also id.* at 570 (noting that plaintiffs must "nudge[] their claims across the line from conceivable to plausible".)

> To state a claim with sufficient specificity " 'requires a complaint with enough factual matter (taken as true) to suggest' the required element." The rule " 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' the necessity element.'"

Secretary of Labor v. Labbe, 319 Fed. Appx. 761, 763 (11th Cir. 2008) quoting *Watts v. Fla. Int'l Univ.*, 495 F.3d. 1289, 1295-96 (11th Cor. 2007) and *Twombly*, 127 S. Ct. at 1965 (emphasis added).

"Generally, notice pleading is all that is required for a complaint." *Exceptional Mktg. Group, Inc. v. Jones*, 749 F. Supp. 2d 1352, 1357-58 (N.D. Ga. 2010) citing to *Lombard's, Inc. v. Prince Mfg., Inc.*, 753 F.2d. 974, 975 (11th Cir. 1985). "Under notice pleading, the plaintiff need only give the defendant fair notice of the plaintiff's claim and the grounds upon which it rests." *Id*. citing to *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) which is citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007).

As one noted scholar pointed out, the Federal Rules of Civil Procedure were intentionally promulgated as notice pleading.

> The Rules had a notice pleading regime that abjured factual detail and verboseness. It demanded relatively little of the pleader…they [the people who wrote the Federal Rules] were deeply steeped in the history of code and common-law procedure, [and] they came to the conclusion that there was very little reason to require endless detail in the pleadings and be bogged down at that early state of the litigation. Let's just get into it was the objective. Let's get into the merits with open discovery; the parties should be permitted to secure access to anything relevant to the subject matter of the action, and each of them was provided equal access to all of that relevant data.

Arthur R. Miller, *Are the Federal Courthouse Doors Closing? What's Happened to the Federal Rules of Civil Procedure*, 43 Tex. Tech L. Rev. 587-588 (2010-2011).

In an effort to avoid litigation involving the death of Chandra Clark who was implanted with one of Defendants' devices, Defendants seek to hold Plaintiff to a "super pleading" standard which is not even called for by *Twombly* and *Ibqal*. Plaintiff will address each of Defendants concerns below.

a. Plaintiff has properly alleged facts regarding the device malfunction, including how these devices have malfunctioned and how this specific device caused Chandra Clark's death

Defendants first argue that Plaintiff has not pled any facts regarding how the device malfunctioned and how such malfunction caused Chandra Clark's death. Plaintiff specifically alleges that the device at issue was recalled after Chandra Clark's death because of two known failure modes (1) premature battery depletion; and (2) defective low voltage capacitor. (SAC ¶ 19.) The FAMC goes into great detail regarding how Defendants' devices work, their components and the knowledge regarding its failures. Without the benefit of discovery on this subject, Plaintiff cannot be expected to describe the specific device malfunction, and that is not the law -- the Court does "not require heightened fact pleading of ***specifics***, but only enough facts to state a claim to relief that is plausible on its face." *Bell Atl.*

Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007) (emphasis added). Even so, Plaintiff did clearly allege the types of malfunctions known to occur with this specific device, and the Defendants' pacemaker devices generally.

As mentioned above, Defendants seek to place upon Plaintiff a "super pleading" standard; however, "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular." *Bausch v. Stryker Corp*., 630 F.3d. 546, 558 (7th Cir. 2010). As the *Bausch* Court recently noted when finding that the district court had erred by dismissing the plaintiff's complaint and denying her leave to amend,

> …district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.

Id.

A fair reading of the SAC together with the FAMC, is that there were known defects in this device and that one of these defects caused Chandra Clark's death. As is pled, "Ms. Clark began to experience bradycardia…which eventually led to cardiac arrest and death because the Model T175 pacemaker malfunctioned and failed to return the heart to its proper rhythm…" ((SAC ¶ 15.) This specifically addresses how the malfunction caused Chandra Clark's death. The defects

discussed in the SAC and FAMC, resulted in a failure of the pacemaker to return Chandra Clark's heart to its proper rhythm leading to her cardiac arrest and death. This clearly meets the standard of putting Defendants on notice of Plaintiff's claims and the grounds of their claims. Plaintiff is not required to prove her case on the pleadings. The SAC, coupled with the FAMC, need only provide enough factual information to "raise a reasonable inference, and thus a plausible claim." *Speaker v. U.S. Dept. of Health & Human Services Centers for Disease Control & Prevention*, 623 F.3d 1371, 1386 (11th Cir. 2010).

b. Plaintiff's reliance on the FAMC is appropriate

Defendants next argue that reliance on the FAMC does not help because it contains no facts regarding Plaintiff's alleged injuries. *Defs. Mem. In Supp.* p. 26. Plaintiff concedes that the FAMC does not contain facts regarding Plaintiff's injuries. The FAMC was filed over a year before the filing of Plaintiff's SAC. It is Plaintiff's SAC that provides the factual details regarding Chandra Clark's death and the Plaintiff's injuries and damages. Plaintiff attached the FAMC as an exhibit to the SAC, and incorporated it by reference, as support for many of the factual details regarding the Defendants' devices, the knowledge the Defendants had of the defects, their violation of federal regulations and other important matters which Plaintiff did not address in her SAC. Even the Defendants seem to concede that

the FAMC contains at least some information connected to the device at issue here. *Defs. Mem. In Supp.* p. 26.

There is no doubt that this Court can consider the FAMC as part of the SAC when considering the Defendants' motion to dismiss. "In evaluating a Rule 12(b)(6) motion to dismiss, the Court ordinarily is limited to consideration of the pleadings in the case and any documents attached to the pleadings." *In re LTL Shipping Services Antitrust Litig.*, 1:08-MD-01895-WSD, 2009 WL 323219 (N.D. Ga. Jan. 28, 2009) citing to *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3dd 1364, 1368-69 (11th Cir. 1997).

III. This Court Should Allow Discovery

Plaintiff believes that the SAC and FAMC read together, fully and sufficiently provide Defendants with fair notice of Plaintiff's claims and the grounds upon which they rest. Further, these claims sufficiently allege parallel claims which survive preemption. However, if the Court is inclined to consider Defendants' arguments, Plaintiff repeats her request in the Second Amended Complaint that discovery be allowed with respect to the preemption issues, before the Court renders a ruling. (SAC § 71).

It is amazing that Defendants seeks to impose a heightened degree of pleading requirement on Plaintiff in this device case, insisting on a high degree of

specificity (a pleading requirement which as the *Bausch* Court notes, does not exist), yet they also argue that Plaintiff should not be allowed any discovery which would allow her to plead parallel claims to Defendants' heightened standard of specificity. As Defendants correctly note, *Twombly* states that discovery is for the finding of "details" and it is details which Defendants seek: i.e. the precise violations of federal regulations, the precise nature of the defect which led to the malfunction which caused Chandra Clark's death. Plaintiff posits that such information can be provided once Defendants are required to produce documents and depositions are taken on these issues. Otherwise, it is difficult to see how this Plaintiff, or any plaintiff, can meet this burden. As the *Bausch* Court again noted, specifications of the FDA's PMA documents are confidential. *Bausch* at 560.

Plaintiff has pled sufficiently to demonstrate that this is no "fishing expedition" given the limited access to information that she has prior to any discovery. "A plaintiff's pleading burden should be commensurate with the amount of information available to them." *Bausch* at 561, quoting Judge Melloy's dissent in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig*., 623 F.3d 1200, 1212 (8th Cir. 2010).[5] If this Court disagrees, Plaintiff respectfully requests that she be allowed to take discovery on these issues.

[5] Other courts which have allowed discovery in similar situations include

IV. Alternatively, Plaintiff Should be Allowed to Amend Her Complaint

The SAC, read with the FAMC, serves FRCP 8's requirement of giving the Defendants fair notice of Plaintiff's claim, parallel claims and a claim for relief that meets *Twombly*'s "plausible on its face" requirement. However, if this Court is inclined to grant Defendants' Motion to Dismiss, and is not inclined to grant discovery to address the deficiencies alleged by Defendants, Plaintiff respectfully requests leave to file an amended complaint. As noted above, Plaintiff's two prior amendment's (one in State court, one in federal court) were to correct typographical errors and information regarding Defendants' corporate status. This Court should exercise its discretion to allow Plaintiff to amend her Complaint to address the deficiencies Defendants allege, pursuant to Fed. Rules Civ. Proc. Rule 15(a). This is particularly so since much of the law which Defendants cite to which requires a higher pleading standard, came after the filing of the SAC.

Allowing the Plaintiff to amend her complaint would be appropriate and beneficial. See *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 794 (on a motion to

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Aaranson v. American Medical Systems, 2010 WL 3603618 (E.D.N.Y. Sept. 7, 2010); *Burgos v. Satiety, Inc.*, 2011 WL 1327684 (E.D.N.Y. April 5, 2011)

dismiss, district court allowed plaintiff to cure alleged deficiencies by allowing plaintiff to file an amended complaint in a Class III medical device case).[6]

CONCLUSION

For all of the above and foregoing reasons, Plaintiff respectfully requests that this Honorable Court deny Defendants' Motion to Dismiss.

Respectfully submitted, this 19th day of August, 2011.

EDMOND & LINDSAY LLP

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[6] Other device cases where plaintiffs were allowed to amend their complaint to allege parallel claims include: *Heisner v. Genzyme Corp*., 2008 WL 2940811 (N.D. Ill. July 25, 2008); *Walker v. Medtronic, Inc.*, 2008 WL 4186854 (S.D. W.Va. Sept. 9, 2008); *Horowitz v. Stryker Corp*., 613 F. Supp. 2d 271 (E.D.N.Y. Feb. 20, 2009); *Burgos v. Satiety, Inc*., 201 WL 4907764 (E.D.N.Y. Nov. 30, 2010);

7.1 CERTIFICATE OF COMPLIANCE

Pursuant to L.R. 7.1D of the Northern District of Georgia. I hereby certify that this document was prepared in Times New Roman font, 14 point, pursuant to L.R. 5.1(C).

This 19th day of August, 2011.

EDMOND & LINDSAY LLP

s/ Roderick E. Edmond
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CERTIFICATE OF SERVICE

I hereby certify that I have on this day electronically filed the foregoing PLAINTIFF'S MEMORANDUM OF LAW IN RESPONSE TO DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT using the CM/ECF system, which will automatically send email notification of such filing to the following attorneys of record:

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This 19th day of August, 2011.

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